
From: Stephen Dressel [/O=REGENERON/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=STEPHEN.DRESSEL]
Sent: Monday, June 27, 2011 2:19:03 PM
To: Thomas Carvette
Subject: FW: Xcenda Presentation
Attachments: RPI_Exposure Analysis(XF) 2011-05-12.pptx

From: Sara Fernandez (SFO) [mailto:Sara.Fernandez@xcenda.com]
Sent: Thursday, May 12, 2011 9:12 AM
To: Amy Cake; Brett Williams (CLT); Robert Terifay; Loreen Brown (EWR); Torey Parsons (CLT); Robert Davis; David Robinson; John Magliocchetti; Abby Cahn; Stephen Dressel; Wing M. Yeung (SFO); Robert Seibert
Subject: RE: Xcenda Presentation

Hi everyone,

We have done a few minor edits to the deck. Please use this updated deck to follow our presentation today.

Sara

-----Original Appointment-----

From: Wing M. Yeung (SFO) **On Behalf Of** Amy Cake
Sent: Monday, May 02, 2011 9:32 AM
To: Amy Cake; Sara Fernandez (SFO); Brett Williams (CLT); Robert Terifay; Loreen Brown (EWR); Torey Parsons (CLT); Robert Davis; David Robinson; John Magliocchetti; Abby Cahn; Stephen Dressel; Wing M. Yeung (SFO); Robert Seibert
Subject: FW: Xcenda Presentation
When: Thursday, May 12, 2011 7:30 AM-9:00 AM (GMT-08:00) Pacific Time (US & Canada).
Where: Tarrytown, Building 7; 71-211

-----Original Appointment-----

From: Amy Cake
Sent: Friday, April 29, 2011 1:24 PM
To: Amy Cake; Robert Terifay; Robert Davis; David Robinson; John Magliocchetti; Abby Cahn; Stephen Dressel; Wing M. Yeung (SFO); Robert Seibert
Subject: Xcenda Presentation
When: Thursday, May 12, 2011 7:30 AM-9:00 AM (GMT-08:00) Pacific Time (US & Canada).
Where: Tarrytown, Building 7; 71-211

Sara from Xcenda will present the PAP Exposure Model and copay assistance options.

Wing Yeung will notify us as to which other Xcenda members will be conferencing in to the meeting and will pass along the dial in information below.

Everyone dials: 1-866-740-1260 (within the U.S.) or 1-303-248-0285 (outside the U.S.)

Participant Passcode: 3130793#

Moderator Passcode (Bob T. has it)

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Exposure Analysis for VEGF Trap-Eye

Prepared for Regeneron: May 12, 2011

Contents

- Project Objectives and Approach
- General Model Inputs and Assumptions
- Copay Options for Medicare Underinsured Patients
- Exposure Projections for VEGF Trap-Eye
- Key Findings and Strategic Recommendations
- Appendix
 - Additional Scenarios

Project Approach and Methodology

- Objectives and Purpose

- Methodology

Objectives and Purpose

- Objectives

- To project the number of VEGF Trap-Eye patients expected to enroll in access programs for 2011–2013 including:
 - Uninsured via Patient Assistance Program (PAP)
 - Medicare underinsured via independent charitable copay foundation (ICCF), PAP, and alternate ideas
 - Commercial underinsured via manufacturer-sponsored copay assistance program
- To evaluate various copay program design options of interest to Regeneron
- To estimate the financial exposure of such programs to Regeneron

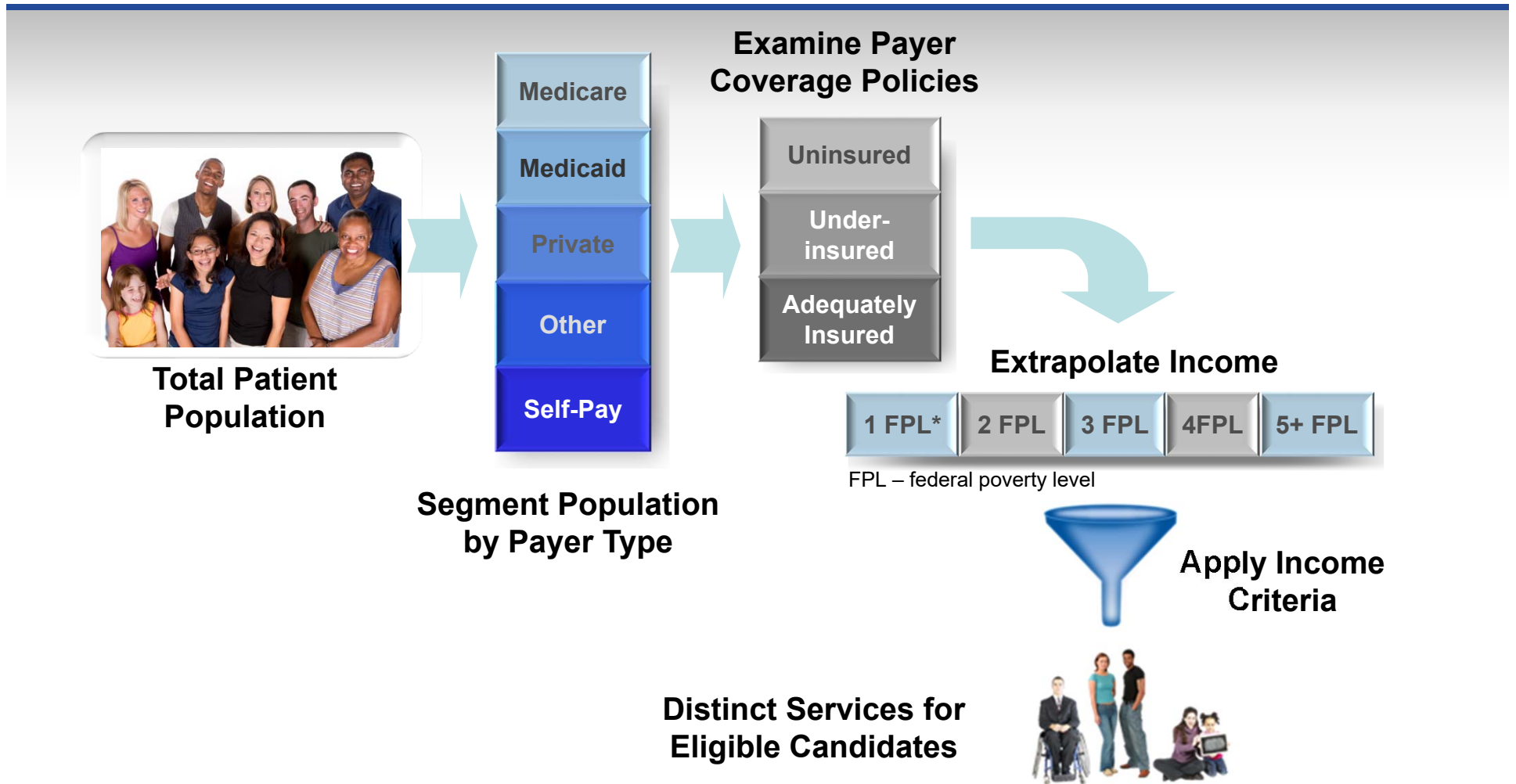
- Purpose

- To provide detailed program size and financial exposure estimates that can be used to inform and guide logistical and budgetary aspects of each product's commercial launch

- Scope

- VEGF Trap-Eye: 2011–2013

General Methodology



Model Inputs and Assumptions: VEGF Trap-Eye

- Patient Population Demographics
- Treatment Assumptions
- Cost Projections and Affordability Measures
- Coverage Assumptions
- Assumptions for Assistance Eligibility and Utilization

New Patient Projections

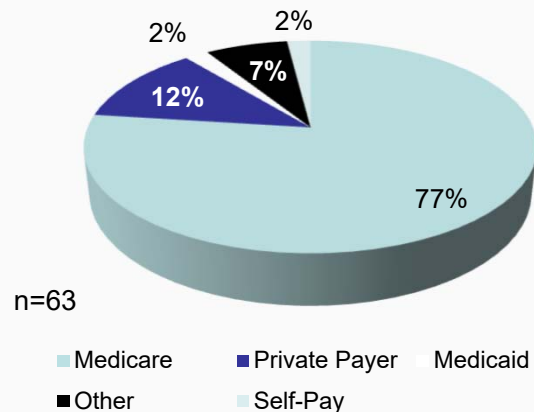
- Patient projections input in the model are based on Regeneron's projections,¹ but spread across the year in quarters, and modified to account for existing patients' continuing therapy in the following calendar year
- Assumption that hardship requirement is based on calendar year vs 12-month period

	Q1	Q2	Q3	Q4
2011	0	0	0	5,430
2012	11,556	6,125	6,125	6,125
2013	31,535	7,033	7,033	7,033

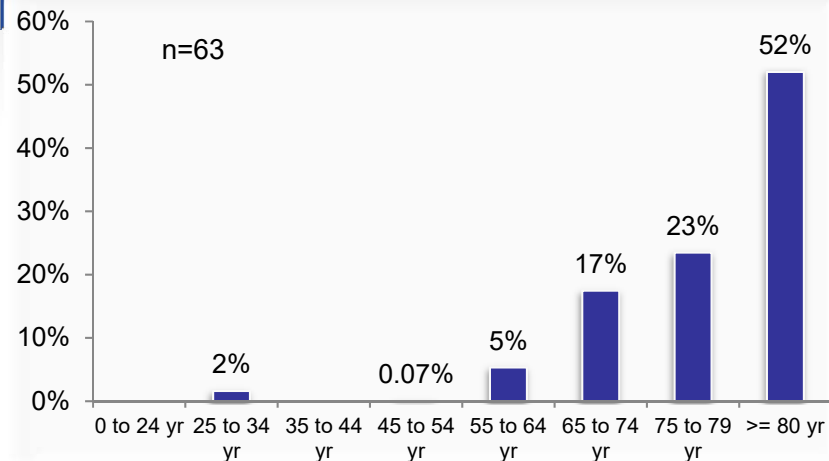
1. Regeneron's patient population projections for VEGF Trap-Eye. AMD and CRVO Dose Forecasts 04-01-11.xls from Stephen Dressel, Regeneron

Wet AMD Payer and Age Mix in the Outpatient Setting¹

Payer Mix (Outpatient)



Age Mix (Outpatient)



- NOTE: As previously discussed with Regeneron, the number of observations is too low (n=63) to be statistically reliable+
- However, as expected, the data indicated that Medicare (77%) is the largest payer for visits with wet age-related macular degeneration (AMD) in the outpatient setting
 - Private payer (12%) and other payers* (7%) account for a small percentage of patient visits
- The data also validated that the vast majority (92%) of patients with wet AMD in the outpatient setting are 65 years of age and older
 - Of these patients, over half are age 80 years and older (52%)

1. Sources: National Ambulatory Medical Care Survey (NAMCS), and National Hospital Ambulatory Care Survey (NHAMCS)

* The data had relative standard of error over 30%; the National Center for Health Statistics (NCHS) considers an estimate to be reliable if it has a relative standard error of 30% or less (that is, the standard error is no more than 30% of the estimate). It should be noted, too, that estimates based on fewer than 30 records are also considered unreliable, regardless of the magnitude of the relative standard error.

VEGF Trap-Eye Therapy Considerations

- Only the cost of VEGF Trap-Eye therapy is considered in affordability calculations
- Assuming 100% compliance rate for a given patient on VEGF Trap-Eye therapy
- Bimonthly dosing following a loading dose yields 7 injections per year
- Two price points (A and B) considered:
 - A = \$1,500 per injection
 - B = \$1,950 per injection

Price Point	Price Per Injection	Annual Cost of Therapy
A	\$1,500	\$10,500
B	\$1,950	\$13,650

Cost Share Assumption Overview

- Definition of underinsured – patient's responsibility for drug copay / coinsurance
 - >5% of household income, or
 - 2.5% if low-income family (defined as <200% FPL)

Patient Category by Payer

Category	Medicare	Private Payer	Medicaid	Self-Pay	Other Payers
Uninsured	7%	0%	0%	100%	0%
High OOP	26%	9%	0%	0%	0%
Low or no OOP	67%	91%	100%	0%	100%

OOP – out-of-pocket expenses

Medicare Cost Share Assumptions

- Estimates of Medicare patients who are underinsured are based upon enrollment in Medigap plans and other supplemental insurance

Medicare

Coverage	Percentage of Patients ¹ 2011	Estimated Cost Share
Part A only	7%	100%
Part B – no supplemental	8%	20%
Part B + employer sponsored	29%	0%
Part B + Medicaid	15%	0%
Part B + other public	1%	0%
Part B + Medigap other	9%	0%
Part B + Medigap Plan F	8%	\$2,000
Medicare Advantage (MA) plan with copay or no cost share ²	15%	\$21
MA plan with coinsurance ²	10%	20%

- MedPAC report to Congress: http://www.medpac.gov/documents/Jun10_EntireReport.pdf
- Source EMD Sereno Specialty Digest 6th Edition

Private Payer Cost Share Assumptions

- Estimates of private payer cost share are based upon specialty drug coverage under the medical benefit

Private Payer

Coverage	Cost Share ¹	Percentage of Patients ¹
No copay / cost share for specialty injectable	\$0	63%
Copay	\$80	28%
Coinsurance	20%	9%

- 85% of the patients will have a maximum OOP threshold estimated at \$3,000 annually^{1,2}

Medicaid Cost Share Assumptions

- Estimates of Medicaid cost share are based upon recent Xcenda research

Medicaid

Coverage	Cost Share	Percentage of Patients ¹
No copay or nominal cost share	\$0 or nominal	100%

- In February 2011, Secretary Sebellius sent a letter to all Governors to discuss potential ways of reducing Medicaid spending including making use of allowed cost-share¹
 - Federal laws allows States to charge Medicaid beneficiaries up to 10% of physician services (including physician administered drugs for patients over 100% FPL, and up to 20% for patients over 150% FPL²
- Initial Xcenda's surveillance of the top 10 states' Medicaid programs found current programs to be still adequate (low or no cost-share)

1. <http://www.hhs.gov/news/press/2011pres/01/20110203c.html>

2. MacPAC Report to the Congress on Medicaid and CHIP – March 2011: <http://www.macpac.gov/reports>

Financial Eligibility Criteria

- Average Household size using according to patient population age mix is 1.9
- Uninsured individuals with $\leq 500\%$ FPL household income
- Underinsured individuals defined as patients with insurance coverage and OOP expenses for VEGF Trap-Eye $> 5\%$ of household income (2.5 % in OOP expenses if household income $\leq 200\%$ FPL)

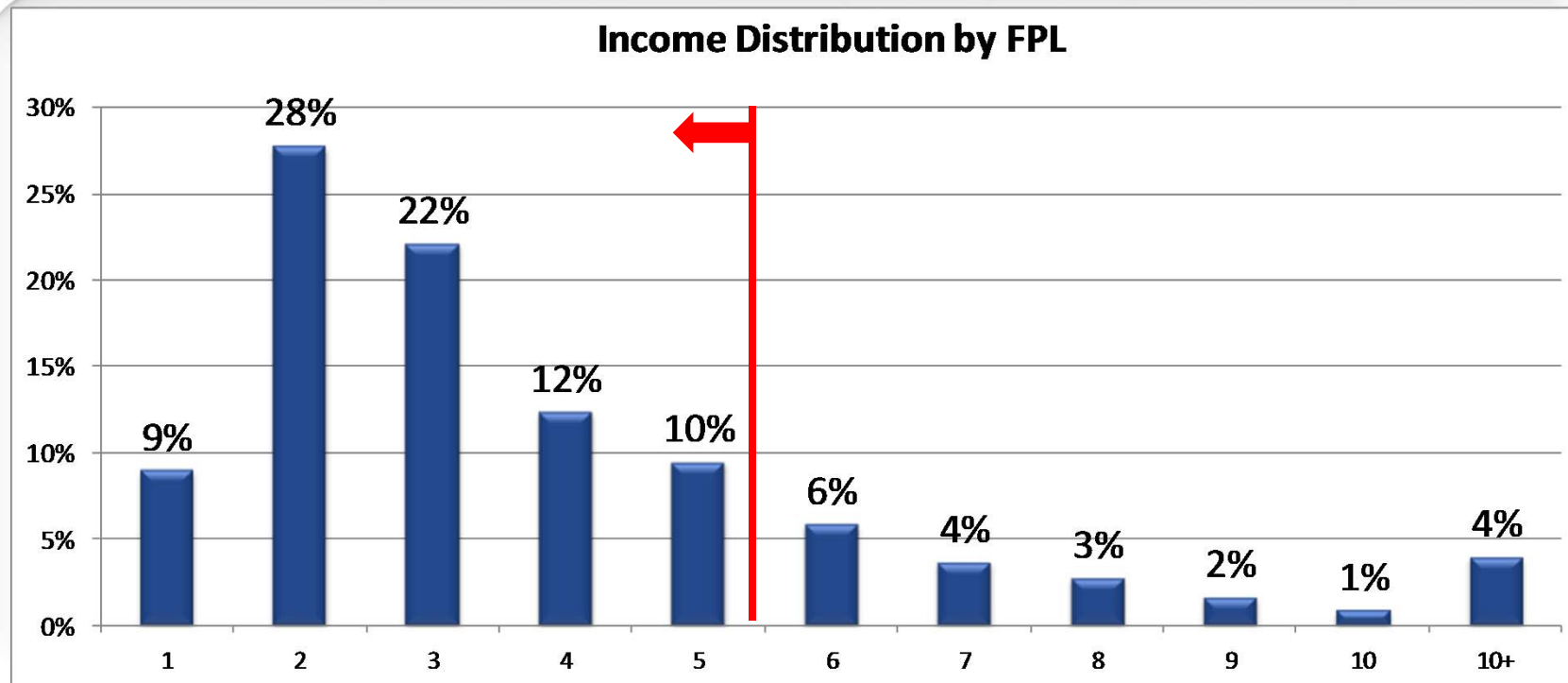
2011 Federal Poverty Levels^{1,2}

Household Size	100% FPL	500% FPL
1	\$10,890	\$54,450
2	\$14,710	\$73,550
3	\$18,530	\$92,650
4	\$22,350	\$111,750
Each additional person	\$3,820	\$19,100

← 1.9 Adj. FPL
= \$14,284

1. Source: US Census Bureau, Current Population Survey, Annual Social and Economic (ASEC) Supplement
2. Figures are for all 48 contiguous states and DC. We will calculate the household size weighted by age mix for the disease state.

Distribution of All Patients Across Income Spectrum



- Approximately 81% of all VEGF Trap-Eye patients would be eligible for assistance if the eligibility criteria is set at 5 times FPL
- Raising the income eligibility criteria to \$100K will increase the eligible patient population to 91%

Other Considerations

- For the PAP financial exposure, cost of goods sold (COGS) is considered to be 5% of WAC
- Administrative costs are estimated to be \$100/year for each patient in the PAP or manufacturer-sponsored copay programs
- Administrative costs for ICCFs are estimated to be 15% of cash donations

Participation Rates

The following participation rates are considered in the analysis:

- PAP program: 60%
- Manufacturer-sponsored copay program: 50%
- ICCFs: 40%
- Medicare PAP: 60%

These participation rates are based on previous Lash experience in running these types of programs and considering a hub model with high-touch services

Assumptions for Assistance Eligibility and Utilization

- The table below summarizes the current assumptions regarding eligibility and participation for each type of assistance program

	PAP	Medicare PAP	Medicare Copay Foundation	Commercial Copay
Patient Population	Uninsured (self-pay + functionally uninsured)	Medicare underinsured (opts in PAP)	Medicare underinsured	Commercial underinsured
Income Criteria	≤500 FPL	≤500 FPL	≤500 FPL	≤500 FPL
Patient Spend-Down Criteria	None	5% of annual household income on OOP costs (2.5% if household income <200% FPL)	\$15/injection	5% of annual household income on OOP costs (2.5% if household income <200% FPL)
Participation Rate	60%	60%	40%	50%

Medicare Copay Support Options

Medicare Copay Support

- Medicare beneficiaries comprise approximately 77% of the treated wet AMD population
- Federal restrictions prevent manufacturers from providing direct financial support to patients covered by federally funded insurance programs
 - Both the Anti-Kickback statute and the Prohibition on Beneficiary Inducement (both under the Social Security Act [SSA]) prohibit “remuneration of any kind in return for purchasing an item for which payment may be made in part under federal healthcare program”¹
 - Establishment of copay support programs outside current models (via “free product” or through an ICCF) would require a favorable OIG guidance letter

1. Sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act as they relate to the commission of acts described in section 1128B(b). Available at: http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#act-1128b-b

Approximately 26% of Medicare Patients Need Help with OOP Costs



- Most Medicare patients have secondary or supplemental insurance coverage to help to cover OOP costs
 - In 2010, ~24% of Medicare Part B beneficiaries were enrolled in MA plans, which do not allow access to Medigap policies¹
 - ~39% of MA plans require patients to pay a coinsurance for specialty drugs²
 - Additionally, approximately 8% of Medicare beneficiaries are enrolled in a Medigap plan F that requires a \$2,000 deductible before coverage begins
 - An additional ~9% of 2010 fee-for-service (FFS) Part B beneficiaries did not have supplemental insurance³
 - We anticipate the rates of underinsured Medicare VEGF Trap-Eye patients will be similar to the overall Medicare population
 - There may be some differential segmentation of patients by selected therapies (eg, most Lucentis patients may have supplemental insurance, while most patients without supplemental insurance may be treated with Avastin)

1. KFF Medicare Advantage Fact Sheet. Available at: <http://www.kff.org/medicare/upload/2052-14.pdf>
2. EMD Serono Specialty Digest 6th Edition
3. MedPAC Report to the Congress: Aligning Incentives in Medicare. Chapter 2 p. 13. June 2010

Underinsured Medicare Patients May be Able to Access Additional Federal Resources



- Honorably discharged veterans and caregivers of post-9/11 veterans may be eligible for additional assistance through Veterans' Affairs (VA) benefits¹
 - According to Census data, there are 22.9 million US veterans²
 - 39.8% of US veterans are 65 years old or older²
 - This represents ~23% of Medicare beneficiaries potentially eligible for assistance if financial eligibility criteria are met
- Low-income Medicare beneficiaries may be eligible for assistance with Part B premium or cost share through the Medicare Savings program³
 - Most low-income Medicare beneficiaries will be already receiving Medicaid benefits; however, some may not be aware of benefits available to them⁴

1. VA eligibility criteria vary based upon a number of factors such as financial eligibility. Available at <http://www.va.gov/healtheligibility/Library/pubs/VAIncomeThresholds/> and http://www.va.gov/opa/publications/benefits_book/benefits_chap01.asp

2. Census Bureau, Current Population Survey 2005-2009. Available at http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-qr_name=ACS_2009_5YR_G00_S2101&-ds_name=ACS_2009_5YR_G00_-redoLog=false

3. Medicare Saving Program information. Available at <http://www.medicare.gov/navigation/medicare-basics/medical-and-drug-costs.aspx>

4. KFF, The Financial Burden of Health Spending by Medicare Households. Available at <http://kff.org/medicare/upload/8171.pdf>

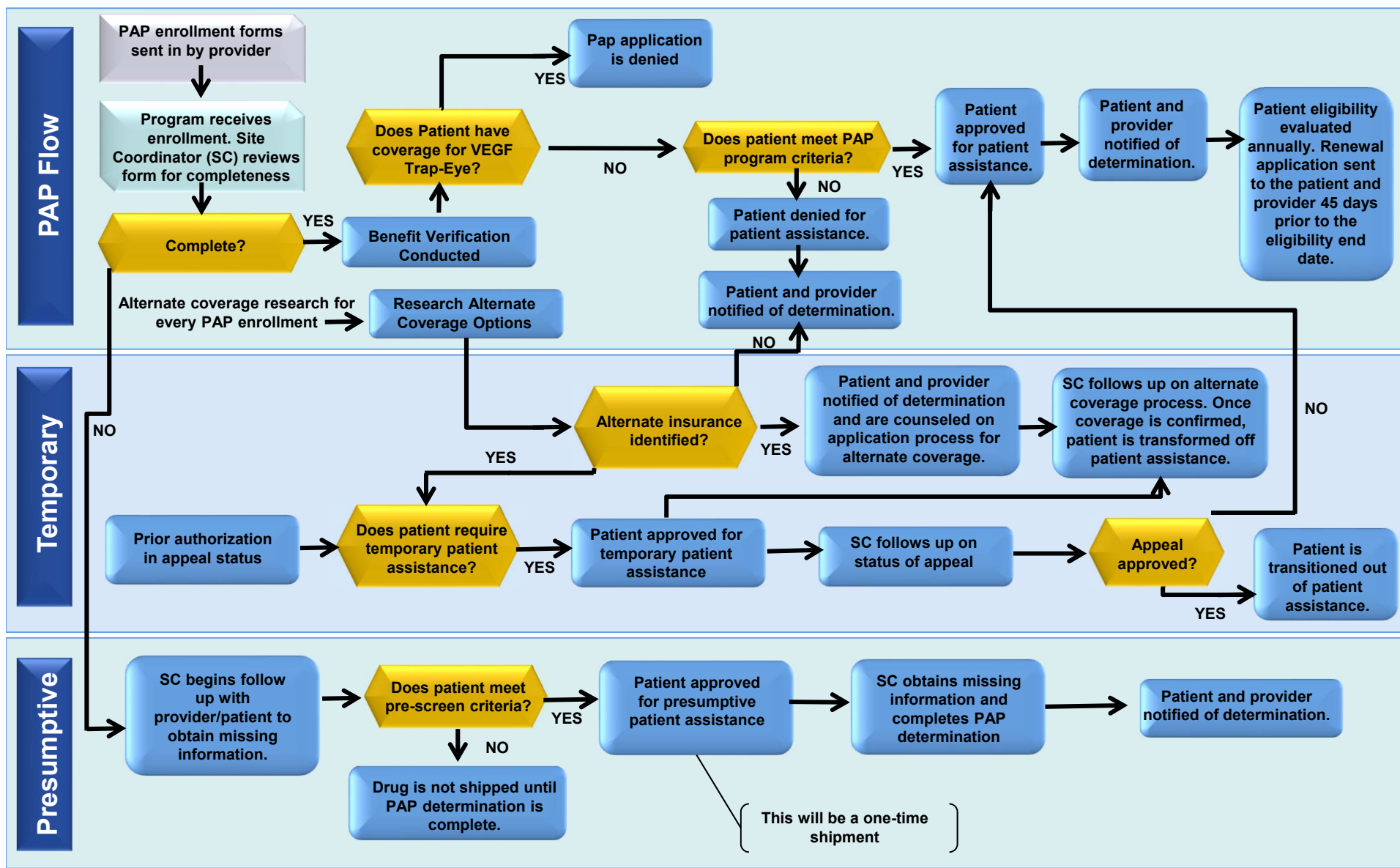
Forms of Copay Foundation Support

- Copay foundations have become a predominate strategy to support underinsured Medicare patients due to restrictions on how manufacturers can assist Medicare patients
- Copay foundations can assist patients with:
 - Grants to pay OOP costs
 - Grants to pay insurance premiums
- Patients hear about copay foundations in a variety of ways
 - Referral from reimbursement hotlines, provider / office staff
 - Copay foundation websites
 - Community / support groups
 - Friends / family

Efforts to Support Needy Wet AMD Patients Will be Well Received by Patients / Providers

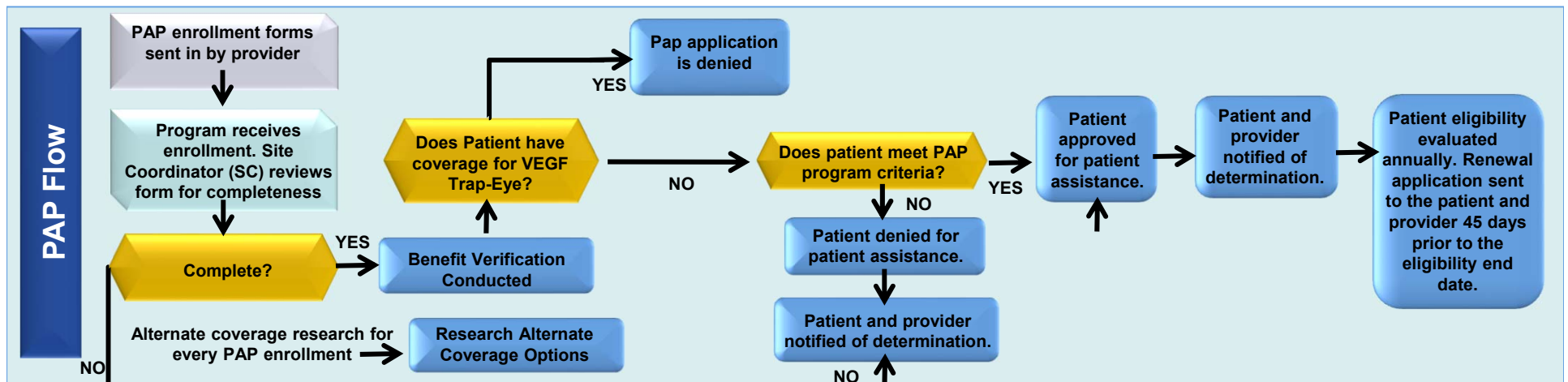
- Genentech does not provide any type of support for Avastin when used for wet AMD
 - Support for Avastin patients is limited to on-label indications
- Providers and patients would welcome additional options to Lucentis given Genentech's previous attempts to block distribution of Avastin for non-oncology indications and Lucentis' high costs and high patient cost-shares
 - Market research with providers may help Regeneron to understand what will be their reaction to the new drug, and the additional services that will be offer through the hotline
 - Additionally, market research may allow Regeneron to have a better estimate of how many of their patients will be sent to copay foundations for assistance allowing Regeneron to adapt the donations accordingly
- Donations to ICCFs coupled with a robust support hotline program, which provides patient case management to ensure enrollment into an appropriate copay program, can be a differentiator for Regeneron

Potential Patient flow



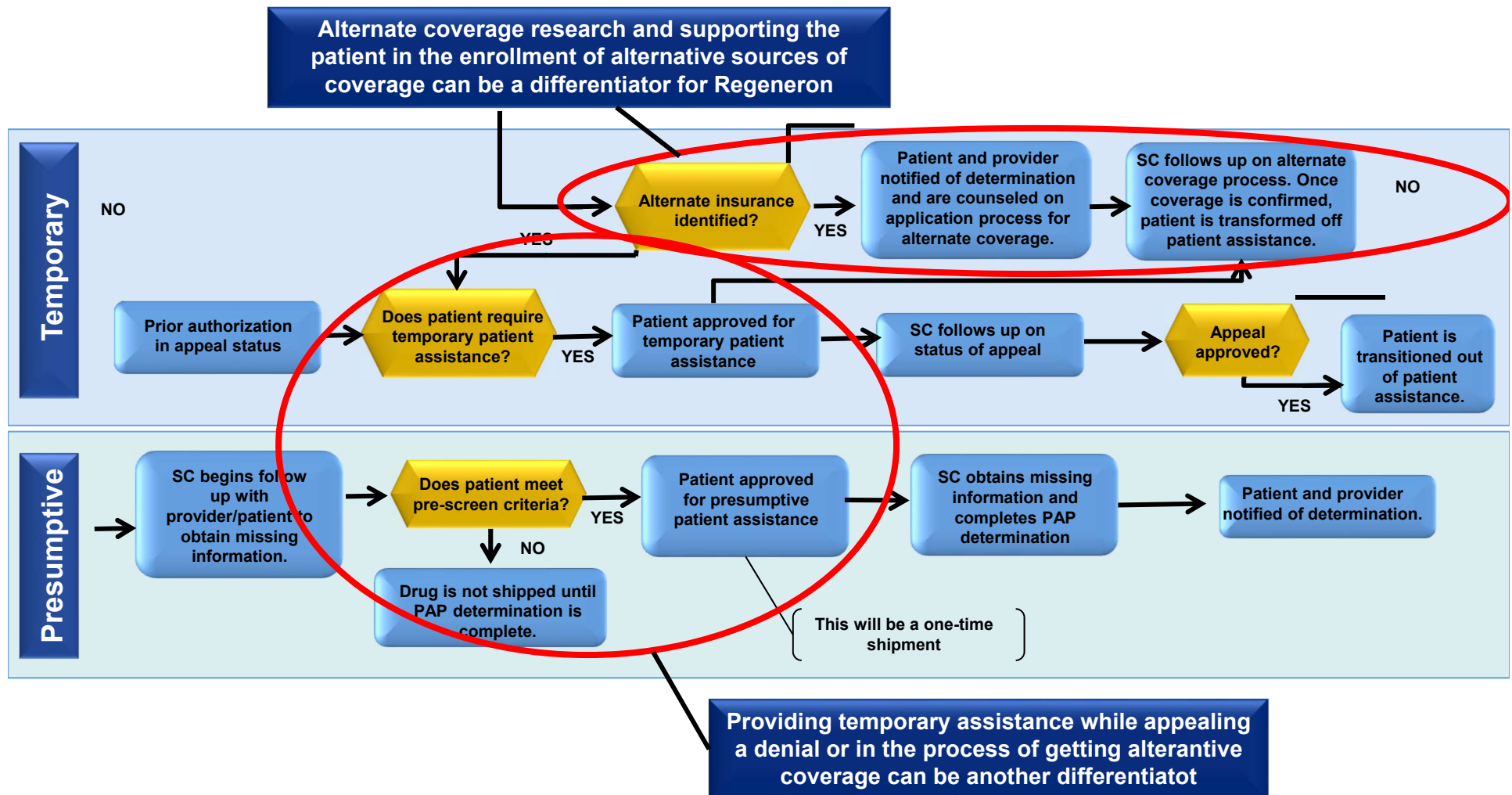
Potential Patient flow

Detail of PAP services

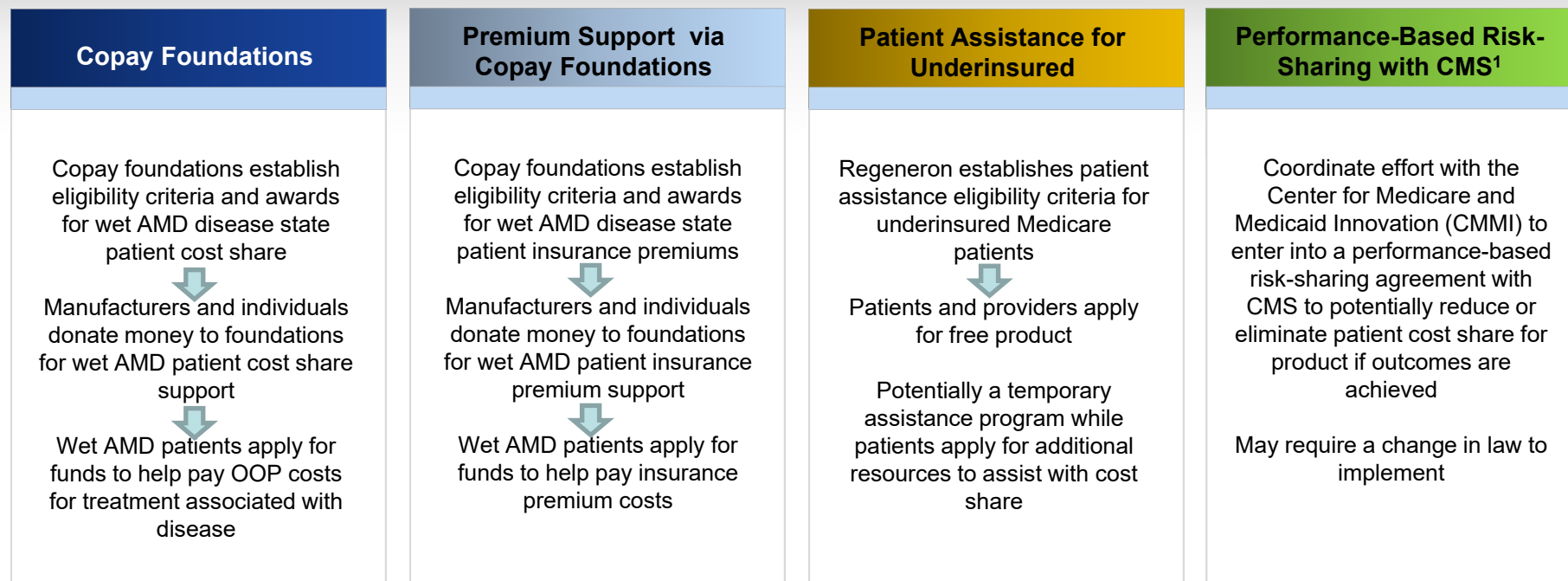


Potential patient flow

Detail of Temporary Assistance and Presumptive PA Services



Medicare Copay Support Options Overview



1. This information is presented for informational purposes only and does not constitute legal advice. Please consult with Regeneron's legal and regulatory counsel for any specific advice.

Copay Foundation Pros and Cons

PROS

- Broad access to therapy
- Simple to work with, internally and externally
- Familiarity of providers and offices with this method of assistance

CONS

- Unknown allocation of funds among products in the same therapeutic space
- Potential loss of patients if funds are depleted

- Copay foundations provide financial assistance to patients diagnosed with certain medical conditions that have high therapeutic costs
- The Assistance Fund, Chronic Disease Fund, Healthwell Foundation, and Patient Access Network Foundation currently have funds set up for AMD
- Insurance premium assistance is available through some foundations for patients, which may be applicable for either primary or purchase of secondary coverage

Patient Assistance for Medicare Underinsured Pros and Cons

PROS

- Positive goodwill public relations by ensuring all patients have access to therapy
- Reduced tax liability

CONS

- Potential sales lost to PAP product
- Support patient on PAP product for remainder of year if alternative funding does not materialize

- Patient assistance (ie, “free product”) could be provided to Medicare beneficiaries as the last resort option
- Eligibility criteria could include screening for VA or Medicare Savings programs and providing 1–2 doses while patients obtain additional assistance
 - Medicare Savings programs include assistance with Part B premiums and/or cost share for patients who meet financial criteria¹
 - VA healthcare may be able to provide patient care including product for free or reduced copayment²

1. Medicare Savings programs include Qualified Medicare Beneficiary (QMB) program which pays for Medicare premium, deductible and coinsurance, Specified Medicare Low Income Beneficiary (SMLI) program, and Qualified Individual (QI) program which pay for Medicare Part B premiums. Available at <http://www.medicare.gov/navigation/medicare-basics/medical-and-drug-costs.aspx?AspxAutoDetectCookieSupport=1>
2. VA eligibility and coverage is dependent upon a number of factors including combat status, income, assets, and caregiver status. Available at <http://www.va.gov/healtheligibility/>

Performance-Based Risk-Sharing with CMS Pros and Cons

PROS

- Opportunity to expand patient base
- Coordination with CMMI may be seen as positive to providers

CONS

- Long road of legislative lobbying with uncertain outcome
- Negative patient outcomes may result in reduced or no payment

- Risk-sharing agreements can include:
 - Linking product payment to patient outcomes (eg, maintained vision acuity)
 - Capping Medicare expenditure per patient
- Reward can be in terms of increased payment for desired outcomes or some other compensation such as reduced patient cost share
- Current legislation does not allow CMS to enter these kinds of agreements,¹ although some examples exist among private payers in the US and national payers outside the US
- The Affordable Care Act (ACA) created CMMI to test innovative payment models to reduce program costs while preserving quality care
- CMMI may be receptive to a demonstration project of performance-based risk-sharing with a manufacturer

Potential Performance-Based Risk-Sharing Scenario

- Performance could be based upon favorable clinical outcomes or limited expenditures
- Information can be obtained through claims data and/or a current quality reporting system (eg, PQRS) or electronic health records
- Providers enrolled in the program receive the full Medicare allowed amounts for the product and will not charge patients or secondary payers coinsurance
 - Positive measures / outcomes could result in Medicare covering the coinsurance
 - Negative measures / outcomes could result in Regeneron covering the full cost of the drug

Two Potential Performance-Based Risk-Sharing Scenarios

- Risk-shared based on outcomes
 - Desired outcome: Maintenance of visual acuity¹ in naïve patients treated with VEGF Trap-Eye
 - If desired outcome is achieved, CMS will pay full price for the drug without any or minimal cost-share to the patient for the duration of the response
 - If desired outcome is not achieved, Regeneron will cover pays 50% of the cost of the drug
-
- Risk-shared based on capped-costs
 - Desired outcome: CMS cost per patient will be limited to 6 injections for the first year
 - In return, CMS will waive any cost-share for the patient
 - Any doses in excess of the recommended 7 doses in the first year will be covered by Regeneron

Performance-Based Risk-Sharing

Next Steps

- Create an internal team including legal, government affairs, and HEOR to assess and determine viability of this approach
- Formulate different options for a risk-sharing agreement with CMS
 - HEOR should take the lead in formulating the agreements based on current clinical data
 - Government Affairs to map out prospective plans to address legislative issues with contingency plans
 - Legal should review all potential agreements and processes and be present at CMS conversations to avoid any legal concerns and be able to provide advice to all the organization in this new field
- Arrange a meeting with CMMI to discuss proposed demonstration project
- Prepare for long timelines (years rather than months)

VEGF Trap-Eye Exposure Analysis

- Uninsured PAP
- Medicare PAP
- Medicare Copay Foundation
- Commercial Copay
- Key Findings

Base Scenario and Variables to Consider

Base scenario
(Alternative scenario)

- The table below summarizes the base scenario and variables to consider. All scenarios are run for year 2012 (first full year of VEGF-Trap in the market)

Patient Population	Uninsured	Medicare Underinsured	Commercial Underinsured
Type of Assistance	Traditional PAP	ICCF donation (Medicare PAP ¹)	Manufacturer-sponsored copay program
Income Criteria	≤500 FPL (\$100K)	≤500 FPL	≤500 FPL (\$100K)
Patient Spend-Down Criteria	No spend-down required	\$15/injection	5% of annual household income on OOP costs (2.5% if household income <200% FPL) (\$15/injection)
Participation Rate	60%	40% (60% of Medicare PAP)	50%
Price of injection	\$1,500 (\$1,950)	\$1,500 (\$1,950)	\$1,500 (\$1,950)
Administrative Costs	\$100/patient per year	15% of donation (\$100/patient per year)	\$100/patient per year

VEGF Trap-Eye PAP Size Projections: 2011–2013

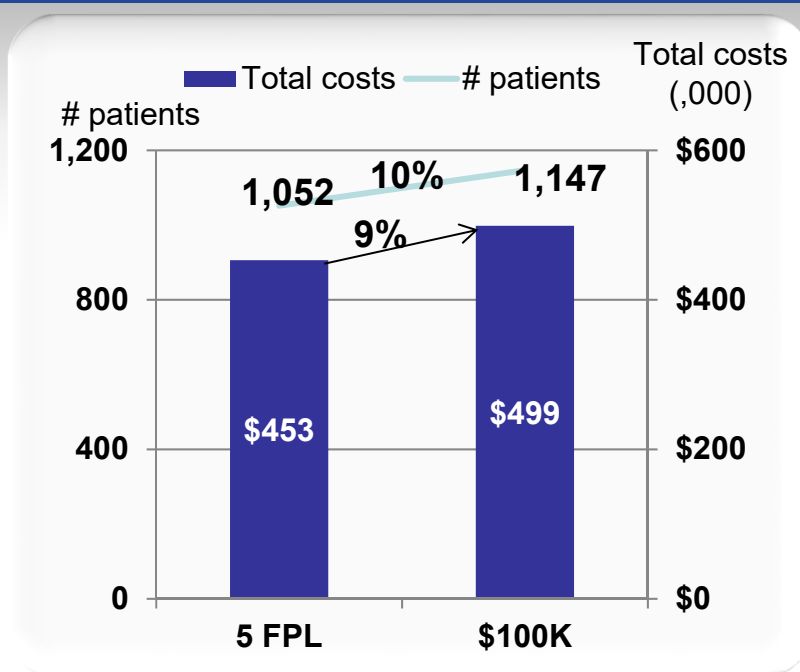
- The table below summarizes projected uninsured VEGF Trap-Eye patient population and financial exposure under a PAP program
 - Income eligibility: ≤500 FPL; participation rate: 60%
 - Base price: \$1,500 per injection

VEGF Trap-Eye Patients				
	Program Size ¹	Free Drug Donation ^{2,3}	Administrative Costs ⁴	Total Cost ⁵
2011	174	\$26,000	\$17,000	\$43,000
2012	1,052	\$348,000	\$105,000	\$453,000
2013	1,924	\$717,000	\$192,000	\$909,000

- In the PAP program, a change in price of therapy has no impact in program size or costs

- Program size takes into account 60% participation rate
- Free drug donation is calculated in terms of cost of goods sold (COGS); COGS = 5% wholesale acquisition cost (WAC) (Regeneron)
- WAC is assumed to be the cost of therapy
- Administrative costs = ~\$100/patient; calculations do not take into account the monthly program management fees (Lash Group)
- Total cost = COGS + administrative cost

Impact of financial eligibility criteria in program size and budget needs



- Increasing the eligibility criteria to \$100K would allow Regeneron to be on par with Genentech's support offerings
 - Moving to \$100K eligibility criteria represents a 10% increase in the program size and 9% increase in the budget needs (approximately \$50K in 2012)
- The estimated budget needs for the PAP program are largely dependent on the COGS of VEGF Trap-Eye
 - If COGS is significantly different from estimated 5% of drug price, the impact of changing financial criteria will also change

- Year 2012. Program size takes into account 60% participation rate
- Based on COGS value provided by Regeneron
- Administrative cost estimated as ~\$100/patient. Total cost is equal to COGS + administrative costs
- Other variables: 1) No spend down of \$15/injection, 3) Participation rate at 60%

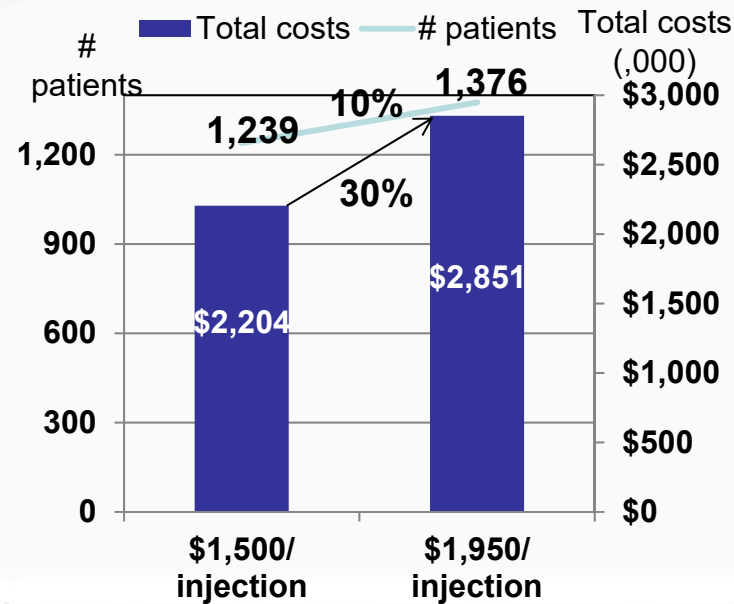
VEGF Trap-Eye Medicare Copay Assistance Foundation Projections: 2011–2013

- The table below summarizes projected underinsured Medicare drug patient population and financial exposure
 - Income eligibility: ≤500 FPL; participation rate: 40%
 - ICCFs will likely factor the OOP costs of other drugs a patient is taking when developing eligibility criteria for the program
 - Increase in copay contribution is due to additional patients' VEGF Trap-Eye copay
 - This is higher in 2012 and 2013 compared to 2011 because some patients will be on therapy for the entire year

VEGF Trap-Eye Only				
	Program Size ¹	Copay Contribution ²	Administrative Costs ³	Total Cost ⁴
2011	162	\$201,000	\$30,000	\$231,000
2012	1,239	\$1,916,000	\$287,000	\$2,203,000
2013	2,362	\$3,868,000	\$580,000	\$4,448,000

- Program size takes into account 40% participation rate
- The copay contribution is the sum of all participating patients' OOP costs
- Administrative cost varies based on foundation (10%–20%) – assumed 15%
- Total cost = copay contribution + administrative costs

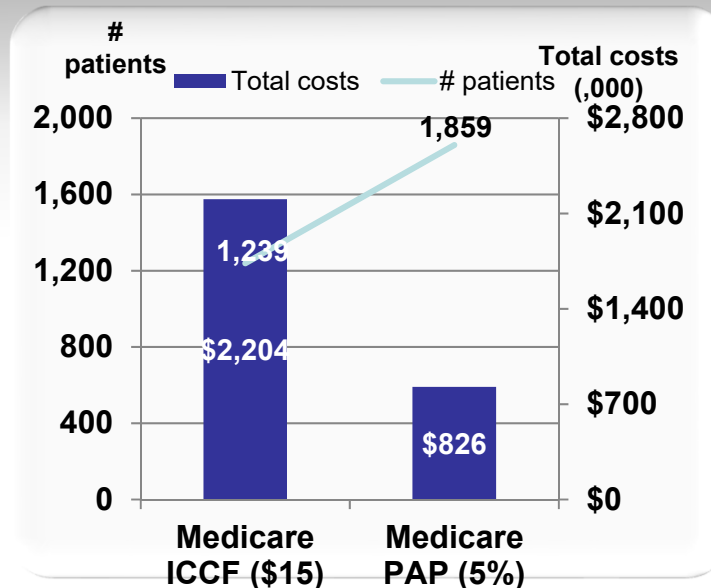
Impact of VEGF Trap-Eye Price on ICCF Program Size and Budget: 2012 Projections



- Increasing the price of therapy from \$1,500/injection to \$1,950/injection increases both the program size and the financial needs to support the ICCF program
 - Program size increases by 10% since there are more patients needing assistance
 - Required donations increase by 37%
- The overall financial impact considering revenue of increasing price to \$1,950/ injection is largely favorable to Regeneron, since the revenue increase will offset the increase in the budget needs to run the program
 - However, increasing the price per injection may create more push back from payers and providers

1. Program size takes into account 40% participation rate
2. Based on COGS value provided by Regeneron
3. Administrative cost estimated as ~\$100/patient. Total cost is equal to COGS + administrative costs
5. Other variables: 1) Income eligibility criteria: household income ≤500% FPL; 2) Fixed spend-down of \$15/injection; 3) Participation rate at 40%

Impact of Type of Assistance for Medicare Patients



- Participation rate at ICCF programs is usually lower since there will be a transfer of the patient from the program to the ICCF (estimated at 40%)
- Participation rate for Medicare PAP program will probably be higher, especially for a hub program (estimated at 60%)
- There is no revenue associated with Medicare patients assisted via the PAP program other than the spend-down required
- Spend-down can limit the financial exposure of supporting patients via the PAP program; however, the financial impact (considering revenue) of a PAP program for Medicare patients would be negative despite requiring a smaller budget

1. Program size takes into account 40% participation rate for ICCF and 60% for PAP for Medicare patients
2. Based on COGS value provided by Regeneron
3. Administrative cost estimated as 15% of ICCF donation, and \$100/patient for PAP total cost is equal to COGS + administrative costs
4. Other variables: 1) Income eligibility criteria: household income \leq 500% FPL; 2) Fixed spend-down of \$15/injection for ICCF and 5% of income for Medicare PAP (2.5% if income $<$ 200% FPL); 3) Price of injection set at \$1,500/injection

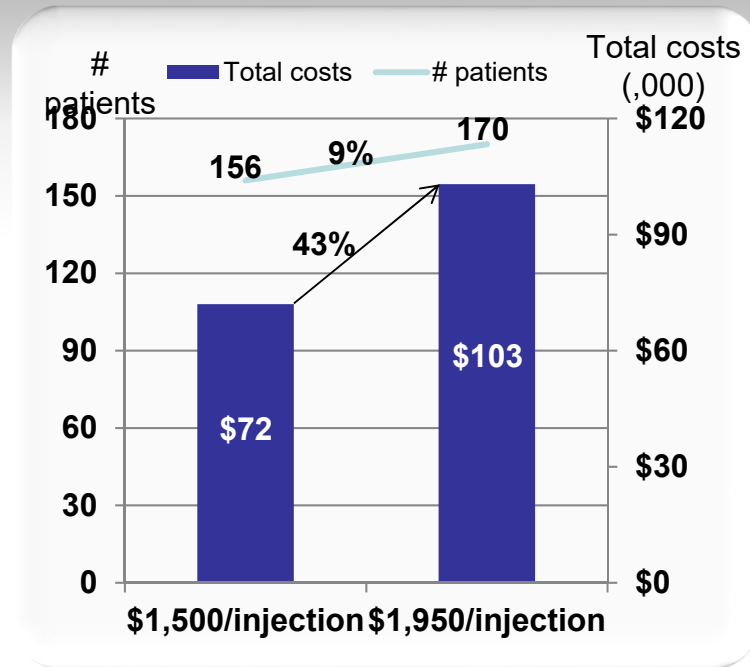
VEGF Trap-Eye Commercial Copay Program Projections: 2011–2013

- The table below summarizes projected underinsured commercial patient population and financial exposure rates
 - Income eligibility: ≤ 500 FPL; participation rate: 50%

VEGF Trap-Eye Only				
	Program Size ¹	Copay Contribution ²	Administrative Costs ³	Total Cost ⁴
2011	7	\$1,000	\$700	\$1,700
2012	156	\$57,000	\$16,000	\$72,000
2013	382	\$148,000	\$38,000	\$186,000

- Program size takes into account 50% participation rate
- The copay contribution is the sum of all participating patients' OOP costs
- Administrative costs = $\sim \$100/\text{patient}$; calculations do not take into account the monthly program management fees (Lash Group)
- Total cost = copay contribution + administrative costs

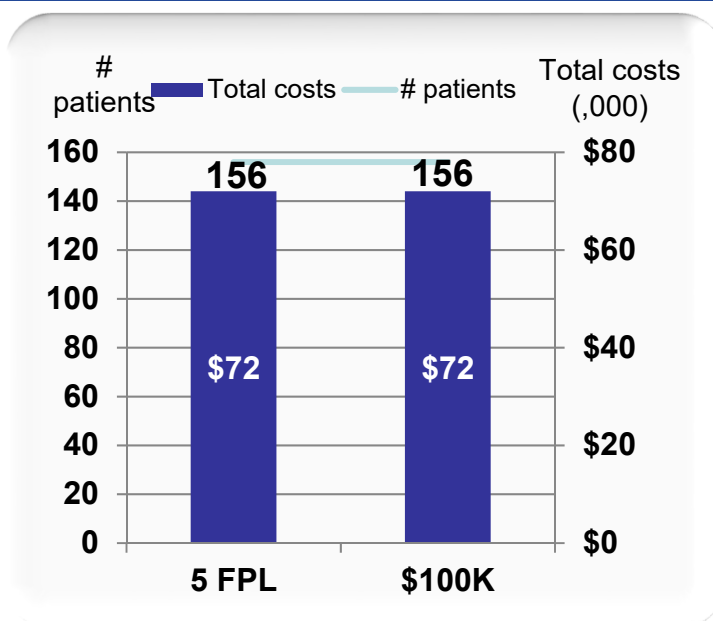
Impact of VEGF Trap-Eye Price on Copay Program Size and Budget: 2012 Projections



- Increasing the price of therapy from \$1,500/injection to \$1,950/injection increases both the program size and the financial needs to support the copay program
 - Program size increases by 9% since there are more patients needing assistance
 - Required donations increase by 43%
- The overall financial impact considering revenue of increasing price to \$1,950/ injection is largely favorable to Regeneron, since the revenue increase will offset the increase in the budget needs to run the program
 - However, increasing the price per injection may create more push back from payers and providers

- Program size takes into account 50% participation rate
- Administrative cost estimated as ~\$100/patient. Total cost is equal to copay donations + administrative costs
- Other variables: 1) Income eligibility criteria: household income ≤500% FPL; 2) Spend-down of 5% of income for Medicare PAP (2.5% if income <200% FPL); 3) Participation rate at 50%

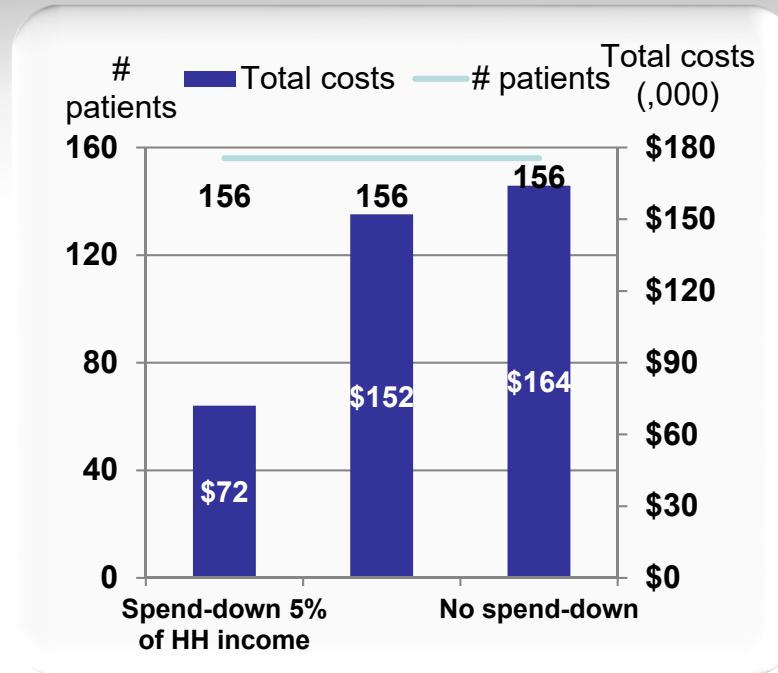
Impact of financial eligibility criteria in program size and budget needs for commercial patients' support



- Increasing the eligibility criteria to \$100K would allow Regeneron to be on par with Genentech's support offerings
- Moving to \$100K eligibility criteria is not expected to affect program size or budget needs since patients over 4FPL are considered adequately insured
 - However, increasing the eligibility criteria to \$100K will allow Regeneron to advertise its program to be as generous as Genentech's

1. Year 2012. Program size takes into account 50% participation rate
2. Wholesale acquisition cost (WAC) is assumed to be the cost of therapy
3. Based on COGS value provided by Regeneron
4. Administrative cost estimated as ~\$100/patient. Total cost is equal to COGS + administrative costs
5. Other variables: 1)) Fixed spend down of \$15/injection, 2) Participation rate at 50%

Impact of Spend-Down on Support to Commercial Patients



- Since the program size for commercial patients is expected to be small, the financial impact of a lower spend-down is relatively minimal
 - The expected difference is \$80-92K in year 2012
- Not having any spend-down can facilitate participation and lower administrative burden and costs for the hotline

1. Program size takes into account 50% participation rate for commercial patients
2. Administrative cost estimated as \$100/patient
3. Other variables: 1) Income eligibility criteria: household income $\leq 500\%$ FPL; 2) Price of injection set at \$1,500/injection

A Note on Participation Rates

- Participation rates will depend on publicity of the program and the resources dedicated to it
 - As more commentary appears in the news, patients are becoming more educated about their options, and participation in these programs may rise
- Factors influencing participation
 - Hub-type model with reimbursement services and PAP services aligned
 - Trainings for Regeneron's sales force and reimbursement specialists
 - Open enrollment for patients, provider staff, or patient advocate (social worker)
 - Easy enrollment form with no stringent documentation requirements
 - Prescriber specialty
 - Prescribers in specialties of high-cost drugs are more familiar with these types of programs and sometimes have specific people on staff to support patients in their applications

Key Findings

Summary of Key Findings

- VEGF Trap-Eye is expected to launch in mainly Medicare market, so the options to support these patients will be very limited due to federal restrictions for these types of patients
 - Regeneron's efforts to differentiate itself from Genentech via a superior high-touch support program will likely be well received by patients and providers
 - Financial eligibility criteria of 500% FPL is in line with main PAP and copay programs and foundations for high-cost specialty program; however, it is lower than current financial criteria for Lucentis
 - Financial eligibility criteria for Lucentis is set at \$100,000 per household, approximately 6.9 times FPL for a household of 2
- Alternative means of support to Medicare patients outside the traditional support through ICCF donations or Medicare PAPs will require a positive OIG guidance and/or the development of a pilot through CMMI; in either case, such a program will not be available at launch
- Of the two traditional options to support Medicare patients, donation to ICCFs seems to be the most favorable option financially due to the loss of revenue associated with providing free drug to Medicare underinsured patients
- Support to underinsured Medicare patients will be critical, and a smooth transition of patients between the hotline and the ICCF will likely increase the utilization of the program and ultimately support Regeneron's reach efforts

Summary of Preliminary Findings

- Increasing the price per injection from \$1,500 to \$1,950 will increase the size and necessary budget requirements for support programs, but it will be offset by the increase in revenue. However, it will be important for Regeneron to consider potential impact of an increase in price to providers and payers
 - PAP is not expected to be affected by a change in price since it will support only uninsured patients
- Requiring a fixed spend-down for commercial patients of \$15 per injection instead of 5% of household income will result in an increase in the budget requirements to support the program; however, given the expected relatively small size of the program, it may be advisable to opt for an administratively simpler program

Strategic Recommendations

Strategic Considerations

- In this section, we address the following strategic considerations:
 - Program Design
 - Program Eligibility Criteria
 - Patient Spend Requirements
 - Medicare PAP vs Medicare Copay Foundation
 - Impact of Healthcare Reform

Recommendation for Program Design

- A high-touch program that follows patients, especially when transitioning to an ICCF, will likely differentiate Regeneron from competitors
 - The hotline may be set up to call the patient at several points during the process of enrollment in an ICCF
 - The hotline should be aware of which ICCFs still have funds available for wet AMD to effectively direct patients to the foundations with the higher chance of enrollment success
 - Regeneron should carefully evaluate existing ICCFs prior to making a donation
- Given the large proportion of Medicare patients and the expected rate of underinsured among these patients, a key component of the support services will be the search for alternate sources of coverage
 - Approximately 23% of Medicare patients may be eligible for assistance from the VA if income eligibility criteria are met
 - Medicare Savings program supports Medicare patients who may need help with their medical expenses but may have an income too high to qualify to be considered dual eligible

Recommendation for Program Design

- Support from the hotline should not be limited to the search of alternate coverage, but also to helping the patient to enroll in these programs and providing temporary assistance
 - Based on the results from the benchmarking analysis, this could be a type of service that could set Regeneron's program apart, since none of Genentech's programs offers these services

Program Eligibility Criteria

- Regeneron should explore the possibility of increasing the income eligibility criteria to \$100,000 per household to be in line with Lucentis' support program
- However, it is important to consider that it is easier to move from a more restrictive program to a less restrictive one than to do the reverse
 - Changing the eligibility criteria of the PAP and manufacturer-sponsored copay program from 5 times FPL to \$100,000 resulted in a marginal increase in patient program size
 - Approximately 81% of patients being treated with VEGF Trap-Eye fall under 5 FPL
- Having PAP and copay assistance programs with the same income eligibility criteria ensures that patients have continued access, despite potential changes in insurance
- Other eligibility criteria, such as residency requirements or who can participate in the enrollment process should not be too restrictive in order to increase participation

Patient Spend-Down Requirements

- Regeneron should consider having a simple, fixed spend-down per injection for the copay program for commercial patients
 - A simple-to-follow spend-down requirement will likely increase participation and reduce administrative burden of the patient and/or provider keeping track of drug expenses
- Regeneron should consider what spend-down is required by the different copay foundations when selecting foundations for contributions

Medicare PAP vs Medicare Copay Foundation

- Based on current assumptions, the most financially viable way of supporting Medicare underinsured patients will be via a donation to a copay charity foundation
 - The loss of revenue associated with providing patients with free drug under the PAP is not compensated by a spend-down
- Donations to copay charities have several limitations, such as no control over which product is supported, limited data provided by the foundation, and no control over operations of the fund (eg, income eligibility criteria or spend-down)
- Regeneron should consider conducting market research with providers to understand their perceptions about the different copay foundations available and their likelihood of sending patients to these foundations in order to better estimate required donations

Impact of Healthcare Reform

- Continue to monitor implementation of healthcare reform efforts, as they will have a great impact on the payer mix and the need for assistance
 - Will Medicaid require additional cost sharing?
 - What will the OOP costs be for patients who enroll in various insurance exchanges? Will those patients have the same restrictions to receive support as federally funded insured patients?
 - How many patients will remain uninsured?
 - How will commercial payer benefit design and cost sharing begin to shift in response to healthcare reform?
 - What new options become available to uninsured patients?
- The operational details of the copay assistance program should complement the benefit design of the program
 - Does a potential change in benefit design warrant changes to operational design or copay mechanism?
 - Good time to evaluate practice experience with current PAP and copay program to see if opportunities for improvement exist
- Regeneron should consider updating this exposure analysis when planning 2013 year cycle after one year of operation, and again in 2013 in preparation for major changes from healthcare reform taking place

Appendix: \$1,950/injection

VEGF Trap-Eye Medicare PAP Size Projections: 2011–2013

- The table below summarizes projected underinsured Medicare drug patient population and financial exposure
 - Income eligibility: ≤ 500 FPL; participation rate: 35%
 - Base price per injection: \$1,500

VEGF Trap-Eye Only				
	Program Size ¹	Free Drug Donation ^{2,3}	Administrative Costs ⁴	Total Cost ⁵
2011	49	\$7,000	\$4,900	\$11,900
2012	494	\$180,000	\$49,400	\$229,400
2013	999	\$398,000	\$99,900	\$497,900

- Program size takes into account 20% participation rate
- Free drug donation is calculated in terms of cost of goods sold (COGS). COGS = 5% WAC (Regeneron)
- WAC is assumed to be the cost of therapy
- Administrative costs = ~\$100/patient; calculations do not take into account the monthly program management fees (Lash Group)
- Total cost = COGS + administrative costs
- Takes into account prescription profile listed in the appendix; average wholesale price (AWP) of other drugs approximately \$500/month